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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/461,938	12/15/99	LIAO S	1279-293/099

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HM12/0523

EXAMINER

HUNT, J

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 05/23/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/461,938

Applicant(s)

Liao et al.

Examiner

Jennifer Hunt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Mar 7, 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 11 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3-8 and 11 is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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***Response to Amendment***

1. Acknowledgment is made of applicant's cancellation of claims 9, 10, and 12. Claims 1-8 and 11 are pending in the application.

***Claim Rejections Withdrawn***

2. All rejections of claims 9, 10, and 12 are withdrawn in light of the cancellation thereof.

3. The rejection of pending claims 1-8 and 11 under 35 U.S.C. 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the unclear recitation of "significant lesions" is withdrawn in light of applicant's arguments and amendments thereto.

4. The rejection of pending claims 1-8 and 11 under 35 U.S.C. 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the unclear recitation of "characterizing fraction" is withdrawn in light of applicant's arguments and amendments thereto.

5. The rejection of pending claims 1-8 under 35 U.S.C. 112 first paragraph for lacking the full scope of enablement, for encompassing diagnosis by amplification and in situ hybridization, is withdrawn in light of applicant's arguments, amendments, and cancellations.

6. The rejection of pending claims 2 and 8 under 35 U.S.C. 112 first paragraph for lacking enablement for the recitation of an absence of MN/CA9 antigen being indicative of a benign lesion is withdrawn in light of applicant's arguments.

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7. The rejection of pending claims 3-8 and 11 under 35 U.S.C. 102(b) as anticipated by Liao et al., Cancer Epidemiology and Biomarkers, Volume 5, pages 549-557, 1996, IDS Document #27 is withdrawn in light of applicant's arguments regarding the specific staining patterns instantly claimed.

8. The rejection of pending claims 3-8 and 11 under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over is withdrawn in light of applicant's arguments regarding the specific staining patterns instantly claimed.

***Claim Rejections Maintained***

9. The rejection of claims 1 and 2 under 35 U.S.C. 102(b) as anticipated by Liao et al., Cancer Epidemiology and Biomarkers, Volume 5, pages 549-557, 1996, IDS Document #27 is maintained for reasons of record.

Applicant argues that Liao et al. fails to teach a method of observing MN/CA9 distribution to discriminating between low grade and significant lesions. Applicant's arguments filed 3-7-2001 have been fully considered but they are not persuasive.

As set forth in the previous Office Action, Liao et al. evaluated MN/CA9 distributions and correlates the staining patterns to AIS (adenocarcinoma in situ) and SIL (which constitutes a significant lesion as defined in the instant application) and further Liao et al. teaches that the absence of MN/CA9 expression in atypical cells and the presence of MN/CA9 expression in NEC (normal epithelial cells) to be indicative of LSIL or dysplasia (atypia) (which constitutes a low grade lesion as defined in the instant application). (See, for example, abstract) Therefor Liao

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et al. does teach a method of observing MN/CA9 distribution to discriminating between low grade and significant lesions.

10. The rejection of claims 1 and 2 under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over is maintained for reasons of record.

Applicant argues that Liao et al. fails to teach a method of observing MN/CA9 distribution to discriminating between low grade and significant lesions. Applicant's arguments filed 3-7-2001 have been fully considered but they are not persuasive.

As set forth in the previous Office Action, Liao et al. evaluated MN/CA9 distributions and correlates the staining patterns to CIN(cervical intraepithelial neoplasia), AIS (adenocarcinoma in situ) and carcinoma (which constitutes a significant lesion as defined in the instant application) and further Liao et al. teaches that the absence of MN/CA9 expression in atypical cells and the presence of MN/CA9 expression in NEC (normal epithelial cells) to be indicative of dysplasia (atypia) (which constitutes a low grade lesion as defined in the instant application). (See, for example, abstract) Therefor Liao et al. does teach a method of observing MN/CA9 distribution to discriminating between low grade and significant lesions.

### ***Conclusion***

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Claims 3-8 and 11 are allowed. Claims 1-2 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Hunt, whose telephone number is (703) 308-7548. The examiner can normally be reached Monday through Thursday 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached at (703) 308-3995. The fax number for the group is (703) 305-3014 or (703) 308-4242.

Communications via internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [[anthony.caputa@uspto.gov](mailto:anthony.caputa@uspto.gov)].


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All internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists the possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist, whose telephone number is (703) 308-0196.

Jennifer Hunt

May 21, 2001

  
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